



NDA 50-710/S-007  
NDA 50-711/S-008

Pfizer Inc.  
Attention: Rita Wittich  
Vice President, Worldwide Regulatory Affairs  
235 East 42<sup>nd</sup> Street  
New York, NY 10017

Dear Ms. Wittich:

Please refer to your supplemental new drug applications dated October 2, 2002, received October 3, 2000, submitted under section 505(b) pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for

NDA 50-710/S-007	Zithromax <sup>®</sup> (azithromycin dihydrate) Oral Suspension
NDA 50-711/S-008	Zithromax <sup>®</sup> (azithromycin dihydrate) Tablets, 250 mg

These applications are subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

We acknowledge receipt of your submissions dated November 21, 2000, March 18, June 28, and July 24, 2002.

These supplemental new drug applications provide for revised Geriatric Labeling in accordance with the August 27, 1997 Federal Register Notice.

We completed our review of these applications, as amended, and they are approved for use as recommended in the agreed-upon labeling, effective on the date of this letter.

The final printed labeling (FPL) must be identical to the package insert submitted on June 28, 2002, and include the following text for the second and third paragraph in the **PRECAUTIONS, Geriatric Use** section. Inclusion of the following text is a term of the approval of these applications.

“In multiple-dose clinical trials of oral azithromycin, 9% of patients were at least 65 years of age (458/4949) and 3% of patients (144/4949) were at least 75 years of age. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.”

ZITHROMAX<sup>®</sup> 250 mg tablets contain 0.9 mg of sodium per tablet.

ZITHROMAX<sup>®</sup> 500 mg tablets contain 1.8 mg of sodium per tablet.

ZITHROMAX<sup>®</sup> for oral suspension 100 mg/5 mL contains 3.7 mg of sodium per 5 mL of constituted solution.

ZITHROMAX<sup>®</sup> for oral suspension 200 mg/5 mL contains 7.4 mg of sodium per 5 mL of constituted solution.”

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Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 50/710/S-007 and NDA 50-711/S-008. Approval of these submissions by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to these NDAs and a copy to the following address:

MEDWATCH, HF-2  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Judit Milstein, Regulatory Project Manager, at (301) 827-2207.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, M.D.,  
Director  
Division of Anti-Infective Drug Products  
Office of Drug Evaluation IV  
Center for Drug Evaluation and Research

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/s/

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Janice Soreth  
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